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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/099,924	03/14/2002	Daniel Albert Wettstein	1909.03	2745

26698 7590 12/02/2004

MYRIAD GENETICS INC.
LEGAL DEPARTMENT
320 WAKARA WAY
SALT LAKE CITY, UT 84108

EXAMINER	
HARRIS, ALANA M	

ART UNIT	PAPER NUMBER
1642	

DATE MAILED: 12/02/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/099,924	WETTSTEIN ET AL.	
	Examiner	Art Unit	
	Alana M. Harris, Ph.D.	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *20 September 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-37 and 39* is/are pending in the application.

4a) Of the above claim(s) *6 and 8-37* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-5, 7 and 39* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *02/11/03; 06/04/04*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Applicant's election of Group I (claims 1-5, 7 and 39 with the second protein being HDLC1) in the reply filed on September 20, 2004 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Applicants are reminded that the Election/Restrictions Requirement mailed August 18, 2004 set forth thirty-five separate and distinct groups. It is not a species election. Applicants cannot elect more than one group for examination as indicated in the reply filed September 20, 2004, "Applicants elect Claims 1-5, 7 and 39 (***Group 1-7*** with second protein being HDLC1)".

2. Claims 1-37 and 39 are pending.

Claims 6 and 8-37, drawn to non-elected inventions are withdrawn from examination.

Claims 1-5, 7 and 39 to the extent that the second protein is HDLC1 are examined on the merits.

Oath/Declaration

3. The declaration filed May 28, 2002 does not include U.S. Provisional Application number 60/307,233 filed on July 23, 2001, however inference to this application is noted on the first line of the specification and the application is listed in the continuing data

section of the bibliography sheet. Applicants are requested to clarify the priority information, review the declaration and verify the request of benefit under 35 U.S.C. 119(e).

Claim Objections

4. Claims 1, 2, 4, 5 and 7 are objected to because of the following informality: they contain non-elected subject matter. Appropriate correction is required.

Specification

5. The first line of the specification does not include a U.S. Provisional Application number for the said application filed on October 25, 2001. Applicants should amend the specification to include all pertinent and proper information.

6. The disclosure is objected to because it contains an embedded hyperlink and/or other form of browser-executable code, see page 17, line 29; page 18, line 5. Applicant is required to delete the embedded hyperlink and/or other form of browser-executable code. See MPEP § 608.01. Applicant should also review the entire specification for similar errors.

Claim Rejections - 35 USC § 112

7. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

8. Claims 1-5, 7 and 39 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Applicants broadly claim an isolated protein complex having a first protein, which is survivin or a homologue, derivative or fragment thereof which interacts with a second protein which is human cytoplasmic dynein light chain 1 (HDLC1) or a homologue, derivative or fragment thereof. The written description in this instant case only sets forth first protein, survivin which is 142 amino acids long (GenBank Accession number U75285) and second protein, HDLC1 which is an 89 amino acid protein (GenBank Accession number U32944), see Table 1 on page 21. Therefore the written description is not commensurate in scope with the claims drawn to an isolated protein complex having homologues, derivatives or fragments of survivin (first protein) and homologues, derivatives or fragments of HDLC1 (second protein). Furthermore, Applicants are only in possession of an isolated protein complex consisting of isolated protein complexes of survivin (amino terminus residues 3-99) and survivin (carboxy terminus residues 89-142) which specifically interact with HDLC1, see the specification, Table 1; page 23, lines 6-31; and page 24, lines 21-24. Applicants are not in possession of any and all homologues, derivatives or fragments of the first and second proteins within an isolated protein complex or fusion protein. The homologues and derivatives more than likely

comprise undefined amino acids that would not resemble the art known proteins, survivin and HDLC1 as defined by their corresponding GenBank Accession numbers.

Vas-Cath Inc. V. Mahurkar, 19 USPQ2d 1111, clearly states that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession *of the invention*. The invention is, for purposes of the 'written description' inquiry, *whatever is now claimed*." (See page 1117). The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (*See Vas-Cath* at page 1116). Applicant is reminded that *Vas-Cath* makes clear that the written description provision of 35 USC 112 is severable from its enablement provision (see page 115).

Applicants are not required to disclose every species encompassed by a genus. For example as indicated in *The Regents of the University of California v. Eli Lilly* (43 USPQ2d 1398-1412), the description of a genus is achieved by the recitation of a representative number of DNA molecules, usually defined by a nucleotide sequence, falling within the scope of the claimed genus. At section B(1), the court states that "An adequate written description of a DNA...'requires a precise definition, such as by structure, formula, chemical name, or physical properties', not a mere wish or plan for obtaining the claimed chemical invention".

Applicant is only in possession of the fragment species of survivin and HDLC1 listed in Table 1, see page 21. Applicants have characterized the 3 sets of bait/binding protein regions of survivin and its interacting partner, HDLC1 prey/interactor protein regions. Applicants are not in possession of unidentified and uncharacterized

homologues, derivatives and fragments thereof of survivin and its interacting partner, HDLC1. Applicants are not permitted to claim all possible peptide combinations comprised within the claimed isolated protein complex or fusion proteins that are encompassed by the claims, hence not entitled to the wide breadth of the claims at issue. As Applicants' claims are written they encompass variants, as well as sequences yet to be discovered. There is no description of the sites at which variability may be tolerated. Structural features that could distinguish the compounds in the genus from others excluded are missing from the disclosure. One skilled in the art cannot reasonably conclude that the applicant had possession of the claimed invention at the time the instant application was filed.

There is insufficient to support the generic claims as provided by the Interim Written Description Guidelines published in the June 15, 1998 Federal Register at Volume 63, Number 114, pages 32639-32645. Applicant is referred to the revised interim guidelines concerning compliance with the written description requirement of U.S.C. 112, first paragraph.

5. Claims 1-5, 7 and 39 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Applicants broadly claim an isolated protein complex having a first protein which is survivin or a homologue, derivative or fragment thereof which interacts with a second

protein which is human cytoplasmic dynein light chain 1 (HDLC1) or a homologue, derivative or fragment thereof. The wild type proteins are depicted in the GenBank Accession numbers referenced on page 21. The claims encompass undefined and uncharacterized protein fragments, fusion proteins, peptides, homologues and derivatives. While one of ordinary skill in the art can theoretically produce all of these proteins with art known techniques such as site-directed mutagenesis it would still be burdensome to one of ordinary skill in the art to produce all of these different combinations and thereafter determine their activity. Likewise, it is not clear what criteria would be used in deciding which amino acids and how many of them would and could be substituted in the wild type proteins and what amino acid residues would represent a survivin or HDLC1 proteins. Granted that is undue experimentation given that this would require a level of ingenuity beyond what is expected from on of ordinary skill in the field. It is art known that certain residues are shown to particularly important to the biological or structural properties of a protein or peptide, e.g., residues in active sites and such residues may not be generally be exchanged.

There is no guidance of record setting forth the strategy of obtaining the broadly claimed isolated protein complex comprising survivin homologues, derivatives and fragments interacting with HDLC1 homologues, derivatives and fragments. The peptide art is unpredictable with regard to determine what peptides resulting form deletions, additions, mutations or analogues would be biologically active. Since the amino acid sequence of a polypeptide determines its structural and functional properties, predictability of which changes can be tolerated in a polypeptide's amino

acid sequence and still retain similar activity requires a knowledge of and guidance with regard to which amino acid or acids in the polypeptide's sequence, if any, are tolerant of modification and which are conserved and detailed knowledge of the ways in which the protein's structure relates to its function. The specification provides essentially no guidance as to which of the infinite possible choices is likely to be successful in making the complex and using the complex in the manner suggested by the specification. The true fact of the state of the art in peptide chemistry is expressed succinctly in the accompanying Lazar article (Molecular and Cellular Biology 8(3):1247-1252, March 1988).

From the discussion above, it is clear that the predictability of changes to an amino acid sequence is practically nil as far as biological activities are concerned. The specification fails to provide sufficient guidance to enable one of ordinary skill in the art to make and use the claimed polypeptides in a manner reasonably correlated with the broad scope of the claims. Without such guidance, the changes which can be made in the protein structure and still maintain activity is unpredictable and the experimentation left to those skilled in the art is unnecessarily and improperly extensive and undue. See *Amgen Inc. V. Chugai Pharmaceutical Co. Lts.*, 18 USPQ2d 1016 and *Ex parte Forman*, 230 USPQ 546 (BPAI 1986).

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claims 1-5, 7 and 39 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

a. The recitations, homologue and derivative in claims 1, 3, 4 and 7 are vague and indefinite.

Conclusion

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Alana M. Harris, Ph.D. whose telephone number is (571)272-0831. The examiner works a flexible schedule, however she can normally be reached between the hours of 6:30 am to 5:30 pm, with alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Siew can be reached on (571) 272-0787. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Alana M. Harris, Ph.D.
29 November 2004

ALANA M. HARRIS, PH.D.
PRIMARY EXAMINER
11/29/2004